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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,571	02/06/2002	Ren-Jin Lee		2638

7590 06/20/2006

Ren-Jin Lee
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Gaithersburg, MD 20878

EXAMINER	
KOPPIKAR, VIVEK D	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/066,571	LEE, REN-JIN	
	Examiner	Art Unit	
	Vivek D. Koppikar	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. Claims 1-15 have been examined in this application. This communication is the first action on the merits. As of the date of this communication no IDS (Information Disclosure Statement) has been filed on behalf of this case.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-15 are rejected under 35 U.S.C. 101. The claimed invention is directed to non-statutory subject matter. The methods of claims 1 and 2 merely recite a process of making certain estimates and determinations from data. It is not clear from body of the claim and the specification whether these determinations or estimates are derived at by using some algorithm or process developed by the inventors or whether the inventors are making a subjective assessment of the data to arrive at the estimates and determinations.

The examiner recommends amending these claims so that they clearly recite how the "estimating" and "determining" steps in the invention are performed.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 5,860,917 to Comanor in view of "Influence of Pharmacokinetic and Pharmacodynamic Principles on Antibiotic Selection" by Zhanel (hereinafter referred to as Zhanel).

(A) As per claims 1-2, Comanor teaches method for estimating the survival or mortality rate of patients with a fatal infectious disease following an antibiotic treatment and methods of providing evidence for treating a fatal infectious disease using the estimated survival rate or mortality rate of the patients (Comanor: Abstract), the methods comprising:

(c) estimating the survival rate or the mortality rate of the antibiotic-treated patients based on (1) the survival rate or the mortality rate of the controlled patients, and (2) the organism (antigen) eradication rate (Comanor: Col. 5, Ln. 49-67).

Comanor does not teach the following steps which are taught by Zhanel: (b) determining a correlation between (1) the organism eradication rate of the antibiotic and (2) the dose regimen of the antibiotic (Zhanel: Abstract—Sentence 3) not does Comanor teach the step (d) of determining the effective dose of regimen of the antibiotic by targeting the survival rate or mortality rate of the antibiotic-treated patients (Zhanel: Abstract—Sentences 2 and 3). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the method of Comanor with the aforementioned step from Zhanel with the motivation of having a more enhanced means of evaluating the efficacy of antibiotics, as recited in Zhanel (Sentence 1).

The combined method of Comanor in view of Zhanel does not teach step (a) determining the survival rate or the mortality rate of controlled patients with the same diseases, the controlled patients receiving no treatment, or receiving a placebo or an inactive treatment. However, the

examiner takes Official Notice that this feature is well known in the art. At the time of the invention, it would have been obvious for one skilled in the art to modified the combined method of Comanor in view of Zhanel with the above mentioned feature with the motivation of having a control group when conducting a study of the antibiotic so that the control group could be used as a baseline comparison against the group receiving the antibiotic.

(B) As per claim 3, in the combined method of Comanor in view of Zhanel the correlation between the organism eradication rate and the antibiotic dose regimen is derived utilizing the characteristics of the patient (Comanor: Col. 5, Ln. 49-53).

(C) As per claims 4-6, the combined method of Comanor in view of Zhanel does not specifically mention the specific diseases and antibiotics that are recited in these claims, however, Comanor recites that the method it teaches is useful for evaluating the likelihood of a patient's responsiveness to a treatment regimen for treating a disease. Therefore, the examiner takes Official Notice that at the time of the invention, it would have been obvious for one of ordinary skill in the art to have used the method of Comanor for determining the effectiveness of one of the recited antibiotics for treating one of the recited diseases with the motivation of having a means of evaluating the likelihood of a patient's responsiveness to a treatment regimen for treating the disease as recited in Comanor (Col. 4, Ln. 50-55).

(D) As per claim 7, in the combined method of Comanor in view of Zhanel the organism eradication rate is the one against the organisms causing the disease or one against similar organisms susceptible to the antibiotic (Comanor: Col. 5, Ln. 12-19 and Ln. 38-68).

(E) As per claim 8, in the combined method of Comanor in view of Zhanel the organism eradication rate is obtained from human and animal studies (Comanor: Col. 5, Ln. 15-19).

(F) As per claim 9, in the combined method of Comanor in view of Zhanel the organism eradication rate reflects time-dependency of the percentage or the ratio of the patients with a positive culture of the organisms, relative to the total number of patients initially infected with the organisms (Comanor: Col. 4, Ln. 16-21 and Claim 10).

(G) As per claim 10, in the combined method of Comanor in view of Zhanel the pharmacodynamic market is AUC/MIC (Zhanel: Abstract—Sentence 4). The motivation of making the above mentioned modification to the method of Comanor is the same as that set forth in the rejection of Claim 1.

(H) As per claim 11, in the combined method of Comanor in view of Zhanel the characteristic of the patient is their age and gender (Comanor: Col. 5, Ln. 49-53).

(I) As per claim 12, in the combined method of Comanor in view of Zhanel the characteristic of the patient is demographic variables (Comanor: Col. 5, Ln. 49-53).

(J) As per claim 13, the combined method of Comanor in view of Zhanel does not teach that the estimated survival rate or the estimated mortality rate in the antibiotic-treated patients are verified by comparing the estimation with the observed survival rate or the observed mortality rate in antibiotic-treated patients, however, the examiner takes Official Notice that the general concept behind this step (comparing the hypothesis (estimate) to actual (observed) date) is well known in the art and at the time of the invention it would have been obvious for one of ordinary skill in the art to have modified the combined method of Comanor in view of Zhanel with this aforementioned step with the motivation of having a means of confirming or rejecting a proposed hypothesis based on the results obtained from the patient trials.

(K) As per claim 14, in the combined method of Comanor in view of Zhanel the correlation consists of statistical equations (Comanor: Col. 6, Ln. 24-46).

(L) As per claim 15, in the combined method of Comanor in view of Zhanel the effective dose regimen is a dose regimen that results in increases in the patient survival or decreases in patient mortality rate (Zhanel: Abstract—All Sentences).

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

"Suboptimal Antibiotic Dosage as a Risk Factor for Selection of Penicillin-Resistant *Streptococcus pneumoniae* : In Vitro Kinetic Model;" by Inga Odenholt discusses various methods of modeling the chances of a patient surviving a disease after they have been treated with a certain antibiotic.

7. Any inquire concerning this communication or earlier communications from the examiner should be directed to Vivek Koppikar, whose telephone number is (571) 272-5109. The examiner can normally be reached from Monday to Friday between 8 AM and 4:30 PM.

If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Joseph Thomas, can be reached at (571) 272-6776. The fax telephone number for this group is (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either

Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

Vivek Koppikar

3/10/2006

C. LUKE GILLIGAN
PATENT EXAMINER